PATENT
Attorney Docket No.: 2356.0011-06

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc ALIZON et al.

Serial No.: 09/041,975

Filed: March 13, 1998

For: VARIANT OF LAV VIRUSES

Group Art Unit: 1648

Examiner: Jeffrey S. PARKIN

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132

1. I, Denise Guétard, state that I am currently a research scientist at Institut Pasteur. I received my Baccalauréat degree at Auxerre in 1971, and my Certificat Général de Biologie at CNAM Paris, in 1976. My field of expertise is HIV research, and I have worked on diagnostic methods for HIV infection, isolation, and characterization of various HIV strains, study of infected lymphocytes, and evaluation of asymptomatic patients with HIV infection.

2. I declare that I have considered the specification and pending claims for this application, as well as the October 27, 1999, Office Action, which are attached as Exhibits 1-3, respectively.

3. I understand that the claims are directed to a purified HIV-1 variant virus. The claims recite structural properties of the HIV-1_{MAL} and HIV-1_{ELI} viruses.

4. The specification describes the isolation of characterization of HIV-1 isolates HIV-1_{MAL} and HIV-1_{ELI}. (Specification at 7, lines 10-24). The specification indicates that the HIV-1_{ELI} strain was isolated in 1983 from a 24-year old woman with AIDS from Zaire, while the HIV-1_{MAL} strain was isolated in 1985 from a 7-year old boy from Zaire. Identification of a source for these two strains shows that they are distinct and that the inventors were in possession of both of them.

5. Additionally, in Figures 3A-3F, Applicants describe the amino acid sequences of the Gag, Pol, Vif, Vpr, Env, and Nef proteins of HIV-1_{MAL} and HIV-1_{ELI} in comparison to HIV-1_{BRU} and HIV-1_{ARV-2}. This demonstrates that the inventors had isolated and sequenced these important viral proteins in HIV-1_{MAL} and HIV-1_{ELI}.

6. In Fig. 4A, Applicants show that both HIV-1_{MAL} and HIV-1_{ELI} differ at the amino acid sequence level from HIV-1_{IIIB}, HIV-1_{BRU}, and HIV-1_{ARV-2} greater than 3.4 % in the entire Gag protein, 3.1% in the entire Pol protein, and 13.0% in the entire Env protein. The specification indicates that Applicants had isolated, determined amino acid sequences for, and compared HIV-1_{MAL} and HIV-1_{ELI} to other known viruses.

Additionally, Figure 4A shows, in the bottom portion, that HIV-1_{ELI} differs substantially from HIV-1_{MAL}, preventing any arguments that strains are identical, or that only one was isolated.

7. It is my opinion that, with this description of the properties of both the HIV-1_{MAL} and HIV-1_{ELI}, one skilled in the art would understand that the inventors had possession of both of these viruses.

8. Furthermore, Applicants' description clearly conveys that Applicants had possession of the claimed genus of HIV-1 variants, in addition to HIV-1_{MAL} and HIV-1_{ELI}.

9. In Figs. 3A, 3C, and 3E, the specific amino acid differences between Gag, Pol, and Env proteins of each of the isolates HIV-1_{MAL}, HIV-1_{ELI}, HIV-1_{BRU}, and HIV-1_{ARV-2} are shown. Using this information, Applicants described variable and conserved regions of HIV-1 Gag, Pol, and Env. (Specification at 10-17). Applicants' comparison of viruses indicated that these viruses are evolutionarily related as diverging from a common origin. (Specification at 17, lines 17-33).

10. Thus, Applicants' described not only HIV-1_{MAL} and HIV-1_{ELI}, but also a group of HIV-1 viruses, which is of greater evolutionary divergence than the group consisting of

HIV-1_{IIIB}, HIV-1_{BRU}, and HIV-1_{ARV-2}. This group of viruses would contain not only HIV-1_{MAL} and HIV-1_{ELI}, but also variants of these viruses. (See Specification at 3, lines 4-5).

11. I believe that the skilled artisan would recognize that additional members of this group of viruses could contain peptides with amino acid sequences of HIV-1_{MAL}, HIV-1_{ELI}, or combinations of the two sequences.

12. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Dated: 22 juin 2000

By: Guétard D
Denise Guétard